IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

John Ieni

Art Unit: 4121

Application No: 10/591,608

Examiner: J. P. Cornet

Confirmation No: 3117

Filed: December 26, 2007

Atty. Docket No: 61368-233549

Customer No:

For: CADASIL TREATMENT WITH

CHOLINESTERASE INHIBITORS

26694
patent trademark office

ELECTION

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Madam:

In response to the restriction requirement set forth in the Office Action mailed March 30, 2009, Applicant hereby elects Group I, claims 1-10. In response to the requirement that species be elected, Applicant elects <u>donepezil</u> (the compound of formula IV in claim 1 and/or its hydrochloride; formula IVa in claim 2) as a cholinesterase inhibitor; and <u>atorvastastin</u> as a HMG-CoA reductase inhibitor, for examination.

Applicant understands that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

The mere fact that a certain thing may result from a given set of circumstances is not sufficient. Id. In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner, in presenting the inherency argument, bears the evidentiary burden and must adequately satisfy this burden. See id. Regarding functional limitations, the Examiner must evaluate and consider the functional limitation, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. See M.P.E.P. § 2173.05(g); In re Swinehart, 169 U.S.P.Q. 226, 229 (CCPA 1971); In re Schreiber, 44 U.S.P.Q.2d 1429, 1432 (Fed. Cir. 1997). If the Examiner believes the functional limitation to be inherent in the cited reference, then the Examiner "must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art." Ex parte Skinner, 2 U.S.P.Q.2d 1788, 1789 (Bd. Pat. App. & Inter. 1986).

Third, the *drawings* of the cited reference must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art. In re Aslanian, 590 F.2d 911, 200 U.S.P.Q. 500 (CCPA 1979).

Independent Claim 1

Each of the independent claims 1, 7, 13, 26, and 27 recite a washer portion having an abutment surface. Specifically, independent claim 1 recites:

a stemmed washer having a washer portion with an abutment surface adapted to abut a surface of a material, a standoff portion integral with the washer portion and configured to extend substantially through the material of a defined

thickness and substantially limit compressive loading on the material, and a retaining portion integral with the washer portion.

In the Office Action, the Examiner equated the foregoing washer portion, standoff portion, and retaining portion of independent claim 1 with a flange 32, a frustoconical underside 36, and a crimp 54 of a pressure ring 16 disclosed by Bydalek. *See* Paper 16, pages 2-4. However, the Bydalek reference does not disclose each and every element of claim 1 as suggested by the Examiner.

First, the Bydalek reference does not disclose a "standoff portion ... configured to extend substantially through the material and substantially limit compressive loading on the material," as recited in claim 1. Instead, the pressure ring 16 of Bydalek specifically creates a centering force and pressure at the interface between the frustoconical undersurface 36 and a complementary depression 38 in the wheel surface 40. See Bydalek, Figs. 1 and 2; Column 2, line 56 – Column 3, line 11. The creation of force and pressure is the very nature of a pressure ring, such as disclosed by Bydalek. Moreover, the claimed standoff portion is configured to extend substantially through the material, whereas the pressure ring 16 of Bydalek engages only a depression 38 in the wheel surface 40. See id. Neither the disclosure nor the drawings of Bydalek suggest that the pressure ring 16 would or could extend substantially through the material beyond the surface 40 in which the depression 38 is formed.

Second, the Bydalek reference does not disclose a "washer portion with an abutment surface adapted to abut a surface of a material," as recited in claim 1. In sharp contrast, the flange 32 of Bydalek never abuts the wheel surface 40. In fact, the flange 32 is incapable of abutting the wheel surface 40, because the pressure ring 16 can only partially engage a material at the frustoconical undersurface 36. See Bydalek, Figs. 1 and

2; Column 2, line 56 – Column 3, line 11. Thus, a substantial gap remains between the flange 32 and the material engaged by the frustoconical undersurface 36. See id.

In view of these omitted features, the Bydalek reference cannot anticipate independent claim 1 or its dependent claims. Accordingly, the Applicants respectfully request the Examiner withdraw the rejection of claims 1, 2, 4, and 6 under 35 U.S.C. § 102(e).

Independent Claim 7

Turning to the next independent claim, amended claim 7 recites:

a base having a washer portion having a material abutment surface, a standoff portion extending from the washer portion, and a retaining skirt portion extending integrally from the washer portion and capturing the peripheral flange of the threaded nut to retain the threaded nut rotatably in assembly with the base, wherein the standoff portion is adapted to limit displacement of a threaded fastener securable to the threaded nut relative to the washer portion.

In the Office Action, the Examiner equated the foregoing washer portion, standoff portion, and retaining skirt portion of independent claim 7 with a flange 32, a frustoconical underside 36, and a crimp 54 of a pressure ring 16 disclosed by Bydalek. See Paper 16, pages 2-4. However, the Bydalek reference does not disclose each and every element of claim 7 as suggested by the Examiner.

The Bydalek reference does not disclose a "washer portion having a material abutment surface," as recited in claim 7. Contrastingly, the flange 32 of Bydalek never abuts a material having the wheel surface 40. See Bydalek, Figs. 1 and 2; Column 2, line 56 – Column 3, line 11. As discussed above, the flange 32 is incapable of abutting the

Page 10

wheel surface 40, because the pressure ring 16 can only partially engage a material at the frustoconical undersurface 36. See id. This results in a substantial gap between the flange 32 and the material engaged by the frustoconical undersurface 36. See id. Therefore, the Bydalek reference does not disclose the material abutment surface recited in claim 7.

For this reason, the Bydalek reference cannot anticipate independent claim 7 or its dependent claims. Accordingly, the Applicants respectfully request the Examiner withdraw the rejection of claims 7-9 and 12 under 35 U.S.C. § 102(e).

Independent Claim 13

Amended independent claim 13 recites:

a base having a washer portion with an abutment surface adapted to abut an outer surface of a material, a standoff portion adapted to extend from the washer portion such that the standoff portion extends substantially through the material of a defined thickness to limit displacement of the externally threaded fastener relative to the washer portion, and a retaining skirt portion extending integrally from the washer portion and capturing the fastener rotatably in assembly with the base.

In the Office Action, the Examiner equated the foregoing washer portion, standoff portion, and retaining skirt portion of independent claim 13 with a flange 32, a frustoconical underside 36, and a crimp 54 of a pressure ring 16 disclosed by Bydalek. See Paper 16, pages 2-4. However, the Bydalek reference does not disclose each and every element of claim 13 as suggested by the Examiner.

Again, as discussed in detail above, the Bydalek reference does not disclose a "washer portion with an abutment surface adapted to abut an outer surface of a material," as

recited in claim 13. In sharp contrast, the flange 32 of Bydalek never abuts the wheel surface 40. In fact, the flange 32 is incapable of abutting the wheel surface 40, because the pressure ring 16 can only partially engage a material at the frustoconical undersurface 36. See Bydalek, Figs. 1 and 2; Column 2, line 56 – Column 3, line 11. Thus, a substantial gap remains between the flange 32 and the material engaged by the frustoconical undersurface 36. See id. For this reason, the Bydalek reference does not disclose the abutment surface recited in claim 13.

In view of this deficiency, the Bydalek reference cannot anticipate independent claim 13 or its dependent claims. Accordingly, the Applicants respectfully request the Examiner withdraw the rejection of claims 13 and 14 under 35 U.S.C. § 102(e).

Rejections Under 35 U.S.C. §103

Under 35 U.S.C. § 103(a), the Examiner rejected claims 1, 2, and 4-6 as unpatentable over Hans (U.S. Pat. No. 3,829,163) in view of Bydalek; claims 1, 2, and 4-6 as unpatentable over Goiny (U.S. Patent No. 4,969,788); claims 5 and 11 as unpatentable over Bydalek in view of Goiny; and claims 26 and 27 as unpatentable over Bydalek in view of Hans. Applicants respectfully traverse these rejections.

Legal Precedent

The burden of establishing a prima facie case of obviousness falls on the Examiner. Ex parte Wolters and Kuypers, 214 U.S.P.Q. 735 (B.P.A.I. 1979). If the Examiner combines the teachings of the prior art to produce the claimed invention, a prima facie case of obviousness cannot be established absent some teaching or suggestion supporting the combination. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a prima facie case, the Examiner must not only show that the combination includes all of the claimed elements, but also a convincing line of reason as to why one of ordinary skill

in the art would have found the claimed invention to have been obvious in light of the teachings of the references. Ex parte Clapp, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988).

Additionally, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P. § 2145. Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959); M.P.E.P. § 2143.01.

Rejection of Claims 1, 2, and 4-6 over Hans-Bydalek Combination

Applicants assert that one skilled in the art would not be compelled, or find it obvious, to combine the teachings of the two references, i.e., Hans and Bydalek. In fact, the references cited by the Examiner teach away from one another. The Hans-Bydalek combination would also change the principle of operation of each respective reference. For this reason, the Hans-Bydalek combination is improper and cannot stand.

Turning to the references, Hans teaches a lug nut 2 having a pyramid-shaped end 2, which is *glued* to a conical receiving section 5 within a wheel sleeve 4. *See* Hans, Fig. 1; Column 1, lines 41-58; Column 2, lines 26-30 and 57-65. Hans further teaches that,

during mounting of a wheel 14 onto a wheel hub 15, the axial force between stud 10 and the lug nut 1 breaks contact with the glue to facilitate tightening onto the hub 15. See Hans, Figs. 2 and 3; Column 2, lines 57-65. Thus, the principle of operation of Hans requires a glued interface between the lug nut 2 and conical receiving section 5.

In stark contrast, the Bydalek reference, as discussed above, discloses a bolt 12 having a flange 22 and a pressure ring 16 having a flange 32, which has a crimp 54 that overlaps the flange 22 of the bolt 12. See column 2, lines 48-61. In this manner, the crimp 54 prevents separation of the bolt 12 from the pressure ring 16, while preserving a degree of play with respect to the longitudinal axis. See id. Thus, the Bydalek reference clearly teaches away from a fixed or glued interface, as disclosed by Hans. Moreover, the principle of operation of Bydalek requires freedom of movement in an inseparable assembly of the bolt 12 and pressure ring 16. See id. This freedom of movement of Bydalek is impossible with the glued interface of Hans. See id.

For these reasons, the proposed Hans-Bydalek combination is improper and cannot stand. Accordingly, the Applicants respectfully request the Examiner withdraw the rejection of claims 1, 2, and 4-6 under 35 U.S.C. § 103.

Rejection of Claims 1, 2, and 4-6 over Goiny

Independent claim 1 recites, *inter alia*, a washer portion, a standoff portion, and a retaining portion, wherein the washer portion has "an *abutment surface adapted to abut a surface of a material.*"

In the Office Action, the Examiner equated the washer portion, standoff portion, and retaining portion of independent claim 1 with a circumferential flange 29, a spherically shaped underside 14, and a peripheral rim 28 of a pressure ring 22 disclosed

by Goiny. See Paper 16, page 5. However, certain claim features are clearly missing from the Goiny reference.

First, the Goiny reference does not disclose a "standoff portion ... configured to extend substantially through the material and substantially limit compressive loading on the material," as recited in claim 1. Instead, the pressure ring 22 of Goiny creates a holddown force at the angled or wedged interface between the spherically shaped underside 14 and a depression 16. See Goiny, Fig. 2; Column 1, lines 9-17 and 66-68; Column 2, lines 1-4. The creation of force and pressure is the very nature of a pressure ring, such as disclosed by Goiny. Moreover, the claimed standoff portion is configured to extend substantially through the material, whereas the pressure ring 22 of Goiny engages only a depression 16 at one side of a component 6. See id.

Second, the Goiny reference does not disclose a "washer portion with an abutment surface adapted to abut a surface of a material," as recited in claim 1. In sharp contrast, the circumferential flange 29 of Goiny never abuts a surface of the component 6. See id. As illustrated in Fig. 2, a substantial gap exists between the circumferential flange 29 and a surface of the component 6. See id.

In view of these deficiencies, the Applicants further emphasize that the omitted features are not obvious over Goiny. The Examiner has not provided any reason to modify the Goiny reference. Applicants stress that the Examiner must provide <u>objective evidence</u>, rather than subjective belief and unknown authority, of the requisite motivation or suggestion to modify the cited reference. *See In re Lee*, 61 U.S.P.Q.2d. 1430 (Fed. Cir. 2002). One of ordinary skill in the art would not be motivated, nor would there by any reason, to modify the pressure ring 22 of Goiny to abut the circumferential flange 29 against the component 6. Accordingly, the proposed modification of Goiny cannot stand.

For these reasons, claims 1, 2, and 4-6 are believe to be patentable over the Goiny reference. Accordingly, the Applicants respectfully request the Examiner withdraw the rejection of claims 1, 2, 4, and 6 under 35 U.S.C. § 103.

Rejection of Claims 5 and 11 over Bydalek-Goiny Combination

Claims 5 and 11 depend from independent claims 1 and 7, respectively. As discussed in detail above, neither Bydalek nor Goiny teaches a washer portion having an *abutment surface*, as recited by independent claims 1 and 7. Both references disclose flanges positioned substantially away from a mounting surface. For example, the flange 32 of Bydalek is incapable of abutting the wheel surface 40, because the pressure ring 16 can only partially engage a material at the frustoconical undersurface 36. *See* Bydalek, Figs. 1 and 2; Column 2, line 56 – Column 3, line 11. Regarding Goiny, a substantial gap exists between the circumferential flange 29 and a surface of the component 6. *See* Goiny, Fig. 2; Column 1, lines 9-17 and 66-68; Column 2, lines 1-4. For these reasons, the cited references fail to teach or suggest, alone or in combination, the features recited in the instant claims. Accordingly, the Applicants respectfully request the Examiner withdraw the rejection of claims 5 and 11 under 35 U.S.C. § 103.

Rejection of Claims 26 and 27 over Bydalek-Hans Combination

Again, Applicants assert that one skilled in the art would not be compelled, or find it obvious, to combine the teachings of the two references, i.e., Bydalek and Hans. In fact, the references cited by the Examiner teach away from one another. The Bydalek-Hans combination would also change the principle of operation of each respective reference. As discussed in detail above, the principle of operation of Hans requires a glued interface between the lug nut 2 and conical receiving section 5. See Hans, Figs. 2 and 3; Column 2, lines 57-65. In contrast, the principle of operation of Bydalek requires freedom of movement in an inseparable assembly of the bolt 12 and pressure ring 16. See

Page 16

column 2, lines 48-61. Thus, the Bydalek reference clearly teaches away from a fixed or

glued interface, as disclosed by Hans. The freedom of movement of Bydalek is simply

not operable with the glued interface of Hans. For this reason, the Bydalek-Hans

combination is improper and cannot stand. Accordingly, the Applicants respectfully

request the Examiner withdraw the rejection of claims 26 and 27 under 35 U.S.C. § 103.

Conclusion

The Applicants respectfully submit that all pending claims should be in condition

for allowance. However, if the Examiner believes certain amendments are necessary to

clarify the present claims or if the Examiner wishes to resolve any other issues by way of

a telephone conference, the Applicants kindly invite the Examiner to contact the

undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: January 13, 2004

Tait R Swanson

Registration No. 48,226

FLETCHER YODER

P.O. Box 692289

Houston, TX 77269-2289

(281) 970-4545